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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,169	11/28/2001	Lawrence Greenfield	07414.0022-01000	5874

7590 04/30/2003

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Washington, DC 20005-3315

EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 04/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/997,169

Applicant(s)

GREENFIELD ET AL.

Examiner

Jezia Riley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-17,22-28,30-33,38-47,52-56 and 59-64 is/are rejected.
- 7) ☒ Claim(s) 8,18-21,29,34-37,48-51,57 and 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## **DETAILED ACTION**

### ***Response to Remarks***

1. Applicants' arguments and amendments, filed on 4/14/03 have been approved and entered. They have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

2. This action contains newly applied rejections and/or objections. Therefore, applicants are hereby informed that the finality of the previous office action, mailed 12/12/02, has been withdrawn, and that prosecution has been reopened.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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4. Claims 1-7, 9-17, 22-28, 30-33, 38-47, 52-56, 59-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Lienau et al. (6,548,256).

Lienau discloses a method and kit for isolating nucleic acids from a nucleic acid containing starting material, where the nucleic acids are released from the starting material and precipitated onto a trapping membrane. The method and kit may be used in the context of isolating genomic DNA from blood and isolating BACs from transformed bacterial cultures. The method includes mixing the starting material with a lysing and denaturing substance for release of the nucleic acid from the starting material. The lysing and denaturing substance of the invention causes the release of the nucleic acids from the intact cells of the starting material. Typically, the lysing and denaturing substance includes a buffering agent, a salt NaCl, NaOAc, KOAc, NH<sub>4</sub>Cl, and the like, or mixtures), a detergent and a protease. The detergent is a quaternary amine cationic detergent, for example, cetyltrimethylammonium bromide (CTAB), and the like, and mixtures thereof, and the protease is Proteinase K. Example I describes the method which comprises: treatment of a blood sample with Proteinase K, cetyltrimethylammonium bromide, polyvinylpyrrolidone and Tris-HCL, pH 8 in a microfuge tube. Blood samples were obtained and preserved with heparin, sodium citrate and EDTA. The mixture was vortexed on high for approximately 5 seconds and incubated in a Thermomixer at 70 degree C, 900 rpm, for 10 minutes. Further alcohol and detergent substance, (70% isopropanol and 30% Tween 20) was added to the supernatant and the sample was vortexed for 5 seconds which is viewed to be inclusive of the neutralizing step of the cationic detergent (see definition of the instant

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specification on page 21, lines 9-12). The method of Example I further comprises adding the sample to a microcentrifuge tube containing a trapping membrane which is viewed to be inclusive of the solid support of instant claim 1. Further a resuspension buffer, (10 mM Tris-HCL, pH 8) was incubated on the membrane for 3 minutes at 70 degree. C. The solution was centrifuged for 1 minute at 12,000 to 16,000.times.g to elute the gDNA which is viewed to be inclusive of the elution step of instant claim 25.

Claims 14-17, 30-33, 44-47, have added functions which the prior art has not analyzed; but given the above 102 rejection analysis substantiating the basic characterization of the composition of the invention being the same as the reference, these added characteristics are presumed to be inherent in the prior art composition.

As it is pointed in *In re Fitzgerald* (205 USPQ), page 594, 2nd col., 1st full paragraph, supports the shifting of the burden of proof to the applicant that the instantly claimed invention is novel and unobvious over the prior art. Since both the prior art and the instant application prepare and use composition which appeared to be identical for isolating nucleic acid.

5. Claims 8, 18-21, 29, 34-37, 48-51, 57, and 58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

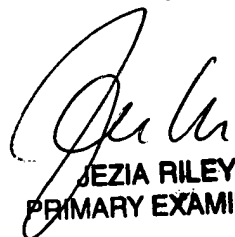
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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855.

The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



**JEZIA RILEY**  
**PRIMARY EXAMINER**

April 29, 2003